ISSUES The

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Comprehensive Cancer Legislation Introduced, Make Your Voice Heard

In March 2009, Senators Ted Kennedy (D-MA) and Kay Bailey Hutchison (R-TX) introduced the 21st Century Cancer ALERT Act (S. 717), a bill designed to improve cancer care in the United States. The bill includes funding for a variety of programs and is intended to promote:

- Greater coordination of care through the use of registries
- Increased access to research and clinical trials
- Increased cancer prevention programs through access to early detection and other screening programs
- Improvements in the coverage of cancer by Medicare and Medicaid
- Increased funding for survivorship programs
- Qualified patient navigation programs.

The bill is a bi-partisan effort that hopefully will gain support throughout the year in both chambers of Congress. ACCC encourages all members to write their elected officials by logging onto ACCC's website at: *www.accc-cancer.org/public_policy/publicpolicy_legislativeaction.asp.* You can then access a letter that you can personalize with details about your cancer program or practice. Send this email to your Congressmen to support the 21st Century Cancer ALERT Act.

ACCC Supports HR 1392, Fair Drug Reimbursement

On March 9, 2009, Representatives Gene Green (D-TX) and Ed Whitfield (R-KY), senior members of the House Energy & Commerce Committee, introduced HR 1392, a bill to change the Average Sales Price (ASP) methodology used by Medicare to set prices for Part B drugs and biologicals to better align drug reimbursement with actual cost.

ACCC strongly endorses HR 1392 and looks forward to working with Representatives Green and Whitfield, and other congressional champions of community cancer care and the broader community oncology and specialty distribution coalition to move this important legislation forward in the 111th Congress. This bipartisan effort will allow for more accurate reimbursement for physicians.

ACCC members can help support HR 1392 by sending an email to Congress. It's easy. From the "Public Policy" section of ACCC's website, select "Contact Washington." Then click on the "Issues and Legislation" tab to email your Congressman.

HR 1392 removes the customary prompt-pay discount extended to wholesalers from ASP. Drug manufacturers are currently required to net out prompt-pay discounts paid to wholesale distributors before reporting ASP figures to CMS, even though the wholesaler prompt-pay discount is not passed along to physicians. Physician drug reimbursements are lowered by approximately 2 percent by this provision in the ASP calculation.

HR 1392 clarifies this statute by removing "customary prompt-pay discounts extended to wholesalers" from the list of price concessions that reduce ASP. The legislation also conforms prompt-pay discount treatment in the ASP methodology to the Average Manufacturer Price (AMP) methodology used to set reimbursement for pharmacies in the Medicaid program. The broader coalition of community oncology and specialty distribution organizations is working together to advance HR 1392.

CMS Revises National Coverage Determination about FDG PET

On April 3, 2009, the Centers for Medicare & Medicaid Services (CMS) announced a national coverage determination (NCD) that expands coverage for positron emission tomography (FDG PET) scans for the management of patients with cancer. Under the NCD, Medicare will cover one FDG-PET study related to initial treatment decisions for patients with essentially all types of solid tumors that are either biopsy proven or are strongly suspected based on other diagnostic testing. Prostate cancer is excluded from this coverage, and certain coverage limitations remain for breast and cervical cancer and melanoma.

On Feb. 4, 2009, ACCC submitted comments supporting the CMS proposed NCD on FDG PET. At the same time, ACCC requested additional coverage enhancements that reflected the current standard of care for patients with cancer. CMS was asked to reconsider Section 220.6 of the NCD Manual to end the prospective data collection requirements across all oncologic indications of FDG PET except for monitoring response to treatment. Section 220.6 of the NCD Manual established the requirement for prospective data collection for FDG PET used in the diagnosis, staging, restaging and monitoring response to treatment for brain, cervical, ovarian, pancreatic, small cell lung and testicular cancers, as well as for cancer indications not previously specified in Section 220.6 in its entirety.

CMS listened. The agency has announced it is revising Section 220.6 of the Medicare NCD Manual to reflect a new framework for most solid tumor oncologic indications and for myeloma.

HOT TOPIC

Leveling the Paying Field

While oral anti-cancer agents currently make up about 10 percent of the oncology market, they are expected to make up 25 percent in the next decade.[1] Many attribute this market increase to patient preference. When given a choice, patients often prefer oral over IV therapy because of such benefits as fewer office visits, reduced burden on family members, and less time spent away from work and home. The downside: high costs that can run in the $6,000 to $8,000 range per patient each month and regimen adherence issues. (For more on the rewards, risks, and challenges oral agents have for community cancer centers, see "Keeping Pace with Oral Chemotherapy," page 36.)

Clinical efficacy and patient safety play a major role in treatment choice; however, three additional influences can affect patient access to clinically appropriate oral therapies:

1. Patient cost-sharing responsibilities
2. Tightly managed pharmacy benefits that place increased administrative burdens on providers
3. The current reimbursement landscape.

Patient Cost-Sharing Responsibilities

Patient copays for oral anti-cancer therapies covered under a payer's pharmacy benefit are often significantly higher than copays for comparable IV therapies. Most patients receiving oral drugs under the pharmacy benefit may pay less for IV therapies because they may be responsible only for an office visit copayment for each IV infusion. Most patients who receive oral drugs under the pharmacy benefit, however, have a separate cost-sharing responsibility—a separate drug copayment.

In cancer treatment, these cost-sharing responsibilities can be significant. Payers assign many oral agents to the fourth tier or specialty tiers; the average copayment for fourth tier drugs is $75 and the average coinsurance rate for fourth tier drugs is 28 percent.[2]

Another challenge for patients: low pharmacy benefit caps. In these situations, patients can rapidly exceed their pharmacy benefit limits, resulting in a significant financial burden. Even worse, monies that patients expend for prescription drug cost-sharing do not always count towards their out-of-pocket maximum, which would enable the patient to access catastrophic coverage.

Today, providers must consider a patient's ability to afford his or her cost-sharing responsibilities when making treatment selections. In other words, a provider may choose an IV over an oral therapy based on knowledge of a patient's ability to afford a specific treatment regimen.

Increased Administrative Burdens on Providers

Tightly managed pharmacy benefits are a burden to busy providers. For example, oral agents often require more prior authorizations than comparable IV therapies. Documentation requirements for oral therapies (e.g., letters of medical necessity, medical records, lab results) are resource intensive for practices. Time spent on documentation and pre-authorizations is also uncompensated.

The Current Reimbursement Landscape

How insurers pay for IV and oral therapies significantly impacts patient access to oral therapies. Often providers are under-reimbursed for oral therapies as compared to IV therapies. Under the "buy and bill" reimbursement model for IV anti-cancer agents, providers are reimbursed for providing infusion services. Unfortunately, at this time, providers are not reimbursed for treatment counseling and management involved in prescribing comparable oral agents that are dispensed by external entities (e.g., specialty, retail, mail order pharmacies).

Oregon Senate Bill 8

In 2007 the state of Oregon passed legislation aimed at addressing payer benefit design disparity, specifically patient out-of-pocket differences between IV and oral anti-cancer therapies.

The issue of coverage disparity was first brought to the attention of the Oregon legislature by a constituent, Heather Kirk. In 2005 Kirk's father was diagnosed with brain cancer and was prescribed an oral anti-cancer agent. As opposed to beneficiaries on his plan on IV therapy who were responsible for a $500 deductible and a $4,000 out-of-pocket maximum, Kirk's father was responsible for a 50 percent coinsurance—with no out-of-pocket maximum. In addition to these out-of-pocket expenses amounting to over $30,000 for a year's worth of oral chemotherapy, Kirk's father also had cost-sharing responsibilities for prescriptions to treat side effects such as inflammation, nausea, fatigue, and seizures.

After appeals to her healthcare plan were denied, Kirk took the issue to the Oregon legislature. She worked with her state representative, lobbyists from the American Cancer Society, and eventually her father's healthcare plan. The result of this collaboration was Oregon Senate Bill 8 (SB 8), which required health benefit plans to equalize patient out-of-pocket responsibilities for oral and IV therapies regardless of the benefit. The exact language of SB 8 specifically states: *A health benefit plan that provides coverage for cancer*

HOT TOPIC

The Private Payer Prognosis

On Saturday March 21, the final day of ACCC's 35th Annual National Meeting, Matt Farber, ACCC's Manager of Provider Economics and Public Policy, engaged attendees in an interactive discussion about recent reimbursement trends, particularly an increasing number of denials and difficulties associated with private payers. The lively forum, "Private Payer Prognosis: Identifying the Problems and Potential Solutions," elicited many responses from attendees. ACCC's goal going forward is to help its membership resolve a growing list of concerns.

"We are seeing prior authorizations on both on- and off-label indications for many commonly used oncology drugs," said one attendee at the presentation. Her concern was echoed by many others in attendance.

A host of other examples of increasing friction between providers and private payers was brought forward:

- "Voluntary" prior authorization that is actually mandatory. (If pre-authorizations are not submitted with every dose the practice has to submit medical records.)
- Uncertain and random payments
- Disclaimers that state authorization is no guarantee of payment, despite the pre-authorization
- Mandates for specialty pharmacy reimbursement
- Diagnostic imaging denials or delays in authorization
- Difficulties with contract negotiations.

Another area of concern is refusal by some private payers to pay for related routine and customary care costs of clinical trials. One attendee noted that a patient had been denied future care because of having once been on an experimental regimen. Attendees agreed that such restrictive private payer policies would make accruing patients to clinical trials, as well as developing new therapies, more difficult.

The consensus among participants seemed to be that private payers are putting up more and more hurdles, thereby blocking or slowing access to anti-cancer therapies.

In the past ACCC has effectively addressed many of these issues with the Medicare program, and the Association would like to do the same with private payers. To that end, the focus of the final segment of the forum shifted to a discussion of what ACCC could do to *help* member providers.

One request was for ACCC to meet or contact private payers about reimbursement policies since some providers may be hesitant to do so on their own. Although such interactions typically deal with specific patients or specific treatment regimens, ACCC has written letters to private payers on behalf of members, and is certainly willing to do so again in the future.

ACCC has working relationships with certain private payers through their medical directors and will attempt to strengthen these relationships and build new ones with other payers. Attendees and ACCC staff agreed that mutual respect between ACCC and the payers is necessary to move forward productively.

Other requests for action centered on getting in touch with local officials, including state insurance commissioners, governors, and state legislators. At the federal level, Senators and Representatives were identified as the best advocates to work on their constituents' behalf. ACCC has a long history of working with elected officials at both state and federal levels and will continue to do so.

In the end, all these efforts are dependent on hearing from ACCC members. We need your help to identify problems with private payers. Please contact Matt Farber at: *mfarber@accc-cancer.org* if you are experiencing difficulties with private payers and have information you would like to share.

chemotherapy treatment must provide coverage for a prescribed, orally administered anticancer medication used to kill or slow the growth of cancerous cells on a basis no less favorable than intravenously administered or injected cancer medications that are covered as medical benefits.

Upon enactment of the bill, Oregon plans subject to the legislation changed their coverage policies accordingly. (This legislation only impacted individual health plans, small group plans that are not self insured, and state employee plans. It did not impact Medicare Part D plans and self-insured group plans which are regulated by ERISA.)

In general, Oregon SB 8 has been positive for beneficiaries. The top state plans eliminated their high coinsurance rates, some established a separate three-tier oral chemotherapy structure under their pharmacy benefit, and, most notably, patients in some plans with no pharmacy benefit now have coverage for oral anti-cancer agents through their medical benefit. It could be said that Oregon SB 8 effectively leveled the "paying field" for oral anti-cancer therapies between a plan's pharmacy and medical benefit and has significantly increased access to life-saving therapies.

2009 State Legislation

Following the passage and implementation of Oregon SB 8, numerous states are actively looking into enacting similar legislation in 2009. Bills addressing the disparity in patient out-of-pocket responsibilities for oral anti-cancer therapies have been introduced in several states and many have heard testimony from stakeholder organizations on the benefit of this legislation, including the American Cancer Society, the Susan G. Komen Foundation, and members of the provider community. If you would like to get involved in such an effort in your state, contact ACCC's Manager of Provider Economics and Public Policy at: *mfarber@accc-cancer.org*.

References

[1]Weingart MD, et al. NCCN task force report: oral chemotherapy. *J NCCN.* 2008;6(3):S1-S14.

[2]Kaiser Family Foundation and Health Research & Educational Trust. 2008 Employer-Sponsored Health Benefits Report. Available online at: *http://ehbs.kff.org/pdf/7790.pdf*. Last accessed April 7, 2009.

Tools of the Trade

by Cindy C. Parman, CPC, CPC-H, RCC

Automobile mechanics have specialized tools to repair cars; pastry chefs have unique tools to create culinary masterpieces; and professional medical coders employ an assortment of tools to ensure that they correctly code and bill for the services performed.

A wealth of books, online programs, and other tools are available to assist and support coding efforts, and trying to decide what should be purchased for an office, facility, or program can be overwhelming. The following is a list of key coding and billing resources no medical coder should be without. Many of the resources listed are available both in hardcopy and electronic format and from multiple publishers or re-sellers.

No discussion about medical coding is complete without a definition of authoritative coding guidance. While opinions on code assignment can be obtained from a number of sources, authoritative coding guidance is only provided by:

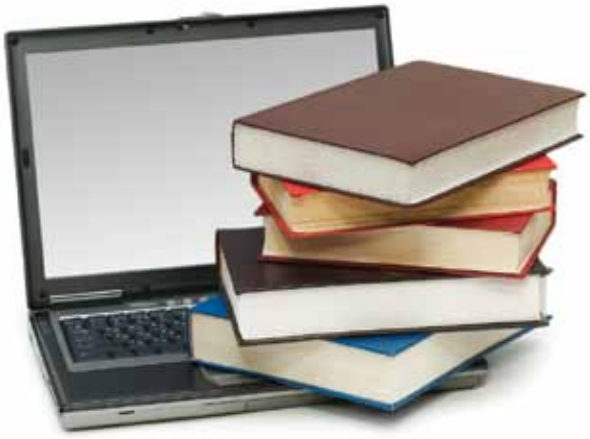
- **The American Medical Association**: The AMA copyrights CPT® codes, and all AMA guidance regarding use of its codes is considered to be authoritative.
- **American Hospital Association**: The AHA publishes official guidance for reporting ICD-9-CM diagnosis codes and will provide data relating to the assignment of ICD-10-CM codes during transition to this new classification.
- **Insurance payers**: These entities are paying benefits for their insured population, and their guidance on coding and billing is considered to be authoritative.

When making a determination regarding coding compliance, consider *all* information and evaluate the *source* of the information. Keep in mind, during an insurance audit or review, it is possible that only authoritative coding guidance will be considered acceptable.

Essential Resources

Resources that every medical coder must have to ensure accurate code assignment include the following.

Medical dictionary and/or anatomy reference. Depending on the medical coder's background and skill level or the complexity of the diagnoses and procedures that require code assignment, having both a medical dictionary and anatomy reference available may be beneficial.



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AMA References. The American Medical Association publishes several different coding references that are essential to code assignment, including:

1. *CPT® Manual*—This reference includes the official procedure code listing for the current year and information on two-digit procedure code modifiers affecting claims payment. Many medical coders prefer the "Professional Edition" because it includes cross-references to other essential publications.
2. *CPT® Assistant*—This monthly newsletter provides valuable information from the AMA regarding the rationale behind procedure code creation and proper utilization. It also includes coding scenarios and questions posed to the AMA for education and communication. Oncology codes are not always referenced in each issue, but over the course of the year, you will find valuable coding information.
3. *CPT® Changes: An Insider's View*—Each year, codes are added, deleted, and/or redefined in the *CPT® Manual.* This resource provides all of the changes, including coding scenarios and the intent of these new codes. Although purchasing this reference on an annual basis may not be necessary, any time oncology codes are added or altered, this book will be invaluable.

Healthcare Common Procedural Coding System (HCPCS) Manual

The Centers for Medicare & Medicaid Services (CMS) developed the HCPCS coding system to standardize coding systems used to process Medicare claims. Healthcare delivery organizations, including physicians, hospitals, and cancer programs must employ these codes when documenting Medicare-related supplies and/or services. An increasing number of private payers also accept or require these Level II codes to provide payment for expenses related to the primary service.

When procedure codes are included in software programs such as hospital encoders or charge description masters, there is often a "short descriptor" comprised of a total of 28 characters. This short definition may not provide complete coding information, requiring the medical coding professional to have sources that provide comprehensive code details.

AHA References

The American Hospital Association publishes the *Official ICD-9-CM Guidelines* and other references for diagnosis coding. In addition, the AHA also offers coding guidance for procedure code assignment in the hospital outpatient department.

1. ***ICD-9-CM Manual***—This resource, which is updated October 1 each year, includes a comprehensive diagnosis code listing. As with other medical coding references, this classification is published in a relatively standard manner and available from various distributors.
2. ***Coding Clinic for ICD-9-CM***—In addition to the *ICD-9-CM Manual*, the AHA also publishes a quarterly reference that answers questions relating to the reporting and sequencing of diagnosis codes and provides in-depth coding information relating to specific clinical scenarios. Most hospitals and large healthcare organizations have *Coding Clinic* information incorporated into the encoder. If it is necessary to purchase this reference separately, it is available both in print and on a searchable disk.
3. ***Coding Clinic for HCPCS***—This publication addresses procedure codes, primarily as they are reported in the hospital outpatient department. Regular features of *AHA Coding Clinic for HCPCS* include coding examples, correct code assignment for new technologies, articles and topics that offer practical information to improve data quality, and a bulletin of coding changes and/or corrections.
4. **Official ICD-9-CM Coding Guidelines**—These guidelines, which are also updated October 1 each year, are available without charge on the Centers for Disease Control and Prevention (CDC) website at: *http://www.cdc.gov/nchs/datawh/ftpserv/ftpicd9/ftpicd9.htm#guidelines*. This 119-page document includes basic guidelines for code assignment, sequencing of multiple diagnosis codes, reporting of signs and symptoms, neoplasm coding, and more.

Medicare References

Both CMS and local Medicare contractors (fiscal intermediaries, carriers, or Medicare Administrative Contractors) publish authoritative coding and regulatory guidance for physicians, freestanding centers, hospitals, and cancer programs, including:

1. **Local Coverage Determinations (LCDs)**—The coder must obtain copies of all LCDs that apply to billed services. LCDs are available on the CMS website as well as directly from the Medicare contractor's website. In addition, many local Medicare contractors provide email notification of changes or updates to existing policies. Coding professionals can ensure that they receive and implement payer updates in a timely fashion by signing up for these free update services.
2. **CMS Internet-Only Manuals (IOMs)**—These electronic manuals include program issuances, policies, and procedures that are based on statutes, regulations, guidelines, and directives. CMS IOMs are a good source of Medicare and Medicaid information for all providers of service. The Internet-only manuals are located at: *http://www.cms.hhs.gov/Manuals/IOM/list.asp*.
3. **National Correct Coding Initiative (NCCI or CCI)**—In addition to regulatory and coding information, CMS also provides information on bundling edits on its website. The NCCI contains two tables of edits: The Column One/Column Two Table and the Mutually Exclusive Table. These include code pairs that should not be reported together for a number of reasons explained in the Coding Policy Manual. CMS also provides information on the correct application of modifier 59, both in the Policy Manual and in separate documents on the NCCI website. The CMS NCCI information is located at: *http://www.cms.hhs.gov/NationalCorrectCodInitEd/*.
4. ***Federal Register***—Most medical coding references address codes and code definitions, but the medical coder may benefit from having access to regulatory documents such as the *Federal Register.* Published by the Office of the Federal Register, National Archives and Records Administration (NARA), the *Federal Register* is the official daily publication for rules, proposed rules, and notices of federal agencies and organizations, as well as executive orders and other presidential documents. When CMS issues a final rule for hospital or physician services, it may include specific coding information, new HCPCS Level II codes, or guidelines on the use of existing codes. *Federal*

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"...correct filing leads to more complete and timely reimbursement."

Register information is located at: *http://www.gpoaccess.gov/fr/index.html*.

Insurance References

In addition to information published by CMS, commercial and managed care insurers publish policy guidelines, coverage information, and medical necessity for various services.

Commercial Insurance Policies—In the not-too-distant past, each insurance agreement or contract included a manual that defined covered services, patient financial responsibility, medical necessity, and other requirements for payment. With today's focus on electronic communication, much of this information is also published on the insurer's website. Each oncology practice, program, or facility is responsible for locating the policy relevant to its patients' treatments and reviewing it to determine whether services will be covered.

Additional Resources

Billers and coders may also want to consider resources developed by specialty societies, professional association, and commercial publishers.

Specialty Societies. Most specialty societies have published coding guidance and documentation recommendations, either in a manual format, Q&A on websites, or through periodic announcements. Although this information may not be considered authoritative coding guidance, it does represent standard-of-practice information for the particular specialty.

Professional Associations. Some specialties have professional organizations for business management and other nonphysician personnel, and many times these organizations have publications, listserves, or other resources.

Private Publications. Many commercial entities publish coding resources; however, careful research should be done before a coding publication is purchased. Is the company reputable? How long has it been in business? Where does it get its information? Just because it is a "specialty" product does not mean that it is accurate and complete—in some cases it may be a compilation of opinions expressed by peers in the same specialty instead of authoritative coding information.

Whatever resources you use, remember that medical code assignment is a complex task that involves an understanding of the clinical service performed and determination of the appropriate procedure and diagnosis codes. The medical coding professional must also take into account regulatory guidance, bundling edits, correct modifier application, and a variety of references and publications to ensure that the insurance claim is complete and accurate. The initial submission of a clean claim serves to expedite payment and eliminates the work associated with researching, refiling, and appealing rejected claims. In a time of economic challenges, correct filing leads to more complete and timely reimbursement.

Cindy C. Parman, CPC, CPC-H, RCC, is a principal at Coding Strategies, Inc., in Powder Springs, Ga.